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510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1a.	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1b.	**Manufacturer Address:** **Mfg. Phone:** **Contact Person:** **Date:**	T.A.G. Medical Products Corporation, Ltd. D. N. Ashrat Kibbutz Gaaton 25130, Israel Tel.: +972-4-985-8400 Erez Adiv February 3, 2012
2a.	**Device Name:**	Knotilus Anchor System
2b.	**Classification Name & code:**	Smooth or threaded metallic bone fixation fastener, class II device (product code MBI ; Regulation number 21 CFR 888.3040)
2c.	**Subsequent Classification Name & code:**	Single/multiple component metallic bone fixation appliances and accessories, class II device (product code LYT ; Regulation number 21 CFR 888.3030)
3.	**Predicate Devices:**	Stryker Endoscopy PEEK TWINLOOP TAC – K070882
4.	**Description:**	The Knotilus Anchor System consists of: • Knotilus Anchor - an implantable anchor preloaded on a disposable inserter to aid with anchor insertion into the bone. The Knotilus Anchor will be offered in outer diameters ranging from 3.5 mm to 6.0 mm and length ranging from 10 mm to 20 mm. • Knotilus Implant Loop - A non-absorbable UHMWPE (Dyneema) loop designed for fixation of soft tissue without the need of knot tying. The Knotilus Implant Loop will be offered with a total length of 470 mm and distal loop sizes of 22 mm, 25 mm and 28 mm. The Knotilus Anchor and Knotilus Implant Loop will be provided separately, sterile for single use only.

5.	**Intended Use:**	The Knotilus Anchor System is intended for use in soft tissue to bone fixation in the repair of the natural ligament or tendon disruption or to assist in reconstruction surgeries. Specific indications are: foot, ankle, knee, hip, hand, wrist, elbow and shoulder.
6.	**Comparison of Technological Characteristics:**	With respect to its indication for use, the Knotilus Anchor System is substantially equivalent to its predicate devices. With respect to technology, the design is similar, as confirmed by comparison, and the performance is the same as verified by design verification. Based upon this, T.A.G. Medical Products Corporation, Ltd. believes that its device is safe and effective because it performs and functions in the same manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

T.A.G. Medical Products Corportation, Ltd.
% MedicSense, USA
Mr. George J. Hattub
291 Hillside Ave.
Somerset, MA 02726

MAR - 2 2012

Re: K113297
Trade/Device Name: Knotilus Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 3, 2012
Received: February 27, 2012

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113297

Device Name: Knotilus™ Anchor System

Indications For Use: The Knotilus™ Anchor System is intended for use in soft tissue to bone fixation in the repair of the natural ligament or tendon disruption or to assist in reconstruction surgeries.

Specific indications are: foot, ankle, knee, hip, hand, wrist, elbow and shoulder.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113297